OFTALMILINE OPTIKA. PAIGALDATUD PRILLILÄÄTSED

Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2017)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21987:2017 sisaldab Euroopa standardi EN ISO 21987:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21987:2017 consists of the English text of the European standard EN ISO 21987:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.08.2017.	Date of Availability of the European standard is 30.08.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.70

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21987

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Supersedes EN ISO 21987:2009

English Version

Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2017)

Optique ophtalmique - Verres ophtalmiques montés (ISO 21987:2017)

Augenoptik - Fertig montierte Korrektionsbrillengläser (ISO 21987:2017)

This European Standard was approved by CEN on 26 May 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 21987:2017 E

European foreword

This document (EN ISO 21987:2017) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2018, and conflicting national standards shall be withdrawn at the latest by February 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21987:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 7944	EN ISO 7944:1998 + AC:2009	ISO 7944:1998 + Cor.1:2009
ISO 8429	EN ISO 8429:1996	ISO 8429:1986
ISO 8598-1	EN ISO 8598-1:2014	ISO 8598-1:2014
ISO 8624	EN ISO 8624:2011 + A1:2015	ISO 8624:2011+ Amd.1:2015
ISO 8980-1	EN ISO 8980-1:2017	ISO 8980-1:2017
ISO 8980-2	EN ISO 8980-2:2017	ISO 8980-2:2017
ISO 13666	EN ISO 13666:2012	ISO 13666:2012
ISO 14889	EN ISO 14889:2013	ISO 14889:2013

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 21987:2017 has been approved by CEN as EN ISO 21987:2017 without any modification.

Annex ZA
(informative)

Relationship between this document and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This document has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this document.

Table ZA.1 — Correspondence between this document and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this document	Remarks/Notes
7.1	5.2, 5.3, 5.4, 5.5, 5.6	5.2 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of toxicity and flammability. 5.3 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of optical performance. 5.4 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of lens thickness. 5.5 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of positioning of the various lens segments. 5.6 of the standard only meets the requirements of Annex I, 7.1 of the Directive in respect of the orientation of polarizing lenses.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this document	Remarks/Notes
9.2	5.2	5.2 of the standard only meets the requirements of Annex I, 9.2 of the Directive in respect of mechanical strength and material ageing.
9.3	5.2	5.2 of the standard only meets the requirements of Annex I, 9.3 of the Directive in respect of flammability.
11.3.1	5.2	5.2 of the standard only meets the requirements of Annex I, 11.3.1 of the Directive in respect of transmittance.
13.1	Clause 7, Clause 9	Clause 7 of the standard only meets the requirements of Annex I, 13.1 of the Directive in respect of permanent or non-permanent marking. Clause 9 of the standard only meets the requirements of Annex I, 13.1 of the Directive in respect of product identification.
13.3	Clause 9	Clause 9 of the standard only meets the requirements of Annex I, 13.3 of the Directive in respect of product trade name and manufacturer address.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this document is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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